May 19, 1993

SIDE-BY-SIDE COMPARISON OF MAJOR PROVISIONS OF SYNAR, WAXMAN AND KENNEDY BILLS TO REGULATE TOBACCO PRODUCTS*

	SYNAR	WAXMAN	KENNEDY
TITLE:	"Fairness in Tobacco and Nicotine Regulation Act of 1993."	"Tobacco Control and Health Protection Act."	"Tobacco Product Education and Health Protection Act of 1991."
DEFINITION OF TOBACCO "ADDITIVE":	"Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any tobacco product."	Same as Synar bill (but uses the term "ingredient," not "additive").	"Any ingredient that is added to a tobacco product in the process of manufacturing or producing a tobacco product."

* This chart compares H.R. 2147 (103d Cong.), introduced by Rep. Mike Synar (D-OK) on May 17, 1993; H.R. 5041 (101st Cong.), sponsored by Rep. Henry Waxman; and S. 1088 (102d Cong.), sponsored by Senator Edward Kennedy (D-MA) and reported favorably by the Senate Committee on Labor and Human Resources on June 16, 1991. Note that Rep. Waxman and Senator Kennedy have not yet introduced comparable bills this Congress. Also note that this chart compares the Waxman bill, as introduced, and not as reported out by his subcommittee in the form of a substitute amendment offered as a compromise by former Rep. Whittaker.

Senator Jeff Bingaman (D-NM) also introduced a tobacco-related bill, S. 672 (103d Cong.), on March 30, 1993. This bill is not included in this chart, but is compared to the Kennedy bill of the 102d Congress (S. 1088) and the Synar bill of the 102d Congress (H.R. 4350) in a chart dated April 8, 1993, a copy of which is attached hereto.

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REGULATORY AGENCY	Amends the Food, Drug, and Cosmetic Act ("FDCA") and grants regulatory authority over tobacco products to the HHS Secretary, who will delegate such authority to the Food and Drug Administration ("FDA"). The FDA, in turn, will act upon the recommendations of the "Tobacco and Nicotine Products Advisory Committee," discussed below. (For the sake of simplicity, this chart hereafter refers only to HHS as the regulatory agency.)	Generally creates a stand-alone law and grants regulatory authority over tobacco products to the HHS Secretary. Since the bill generally does not amend FDCA, it is not clear that HHS would delegate this authority to the FDA. Creates a "Center on Tobacco and Health" within HHS' Public Health Service. (This chart hereafter refers only to HHS as the regulatory agency.)	Amends the Public Health Service Act, creating a new subtitle titled "Prohibited Acts, Enforcement, and Additives," and creates a new "Office of Regulatory Affairs" within HHS' Public Health Service to carry out the new subtitle. Also creates a "Center for Tobacco Products" to carry out the proposed Act's programs. (This chart hereafter refers only to HHS as the regulatory agency.)
REGISTRATION:	Requires tobacco manufacturers to register with HHS not later than 120 days after the Act's enactment.	No comparable provision.	No comparable provision.

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USER FEES:	Charges tobacco companies annual user fees to pay for the FDA's salaries and expenses in implementing the Act. Fees will be specified in annual appropriations acts and will be determined by HHS based on the total market share for each tobacco product brand.	No comparable provision.	No comparable provision.
ADVISORY COMMITTEE:	Establishes a "Tobacco and Nicotine Products Advisory Committee" within the FDA to assist HHS in developing regulations governing "the manufacture, distribution, sale, labeling, and advertising and promotion of tobacco products which are consistent with the manner in which other products which are ingested into the body are regulated, except that HHS may not promulgate a regulation which prohibits the sale and distribution of a tobacco product solely on the basis of the fact that tobacco causes disease."	No comparable provision.	No comparable provision.

(Emphasis added.) Such regulations are to be promulgated no later than one year after HHS receives the recommendations of the Advisory Committee.

The Committee must consist of 10 members appointed by the Secretary, within 60 days from enactment, comprised of one expert from each of the fields of nicotine addiction, pharmacology, food and drug law, marketing and promotion of products, public education, and toxicology, and two each from the public health community and the field of medicine.

Ex-officio members include the Directors of the National Cancer Institute; the National Heart, Lung and Blood Institute; the National Institute of Drug Abuse; the Centers for Disease Control and Prevention; and the Surgeon General. The chairman will be appointed by the HHS Secretary with the FDA Commissioner's advice and consent.

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	The Committee's functions include reviewing (i) the available scientific evidence on the health effects of tobacco products, including environmental tobacco smoke ("ETS"); (ii) the manufacturing process of tobacco products (e.g., sprayed on chemicals and product development), (iii) the role of nicotine; (iv) tobacco companies' marketing techniques; and (v) current federal, state and local laws governing tobacco products. The Committee is authorized to hold hearings, sit and act, take testimony and receive evidence as it deems appropriate.		
DEFINITION OF "CONSTITUENT":	"Any element of cigarette mainstream or sidestream smoke which is present in quantities which represent a potential health hazard or where health effect is unknown."	Same as Synar bill.	No definition because bill refers only to tar, nicotine and carbon monoxide.

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ADDITIVE REGULATION:*	Gives HHS authority to promulgate regulations, but such regulations must contain the following minimum requirements: (i) they must require that all additives are "safe; (ii)) they must classify as a drug any nicotine-containing product not meeting the definition of tobacco product; and (iii) they must have the authority to subpoena any document which relates to the manner in which tobacco products are manufactured.	Gives HHS authority to ban or limit any ingredient that, by itself or in conjunction with any other ingredient, is "unsafe or presents increased risks to health to the consumer or general public."	Gives HHS authority to ban or limit any additive that, by itself or in conjunction with any other additive, "significantly increases the risk of the product to human health." Declares additives in violation of such requirements to be adulterated, borrowing that term from the FDCA, but not amending that Act. Also requires notice and comment procedures (under the Administrative Procedure Act) to be followed before a regulation banning or limiting an additive may be issued, and provides for judicial review of such determinations in accordance with the FDCA.

*Note that, under the general authority granted to HHS to promulgate regulations to govern the "manufacture" of tobacco products, HHS could expand upon the minimum requirements imposed on additives and constituents, as specified in the Synar bill.

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ADDITIVE DISCLOSURE:			
To Agency:	Does not expressly require manufacturers to provide additive lists to HHS, but, as discussed above under "Advisory Committee", generally authorizes HHS to promulgate regulations to govern the manufacture, distribution, sale, labeling . . . of tobacco products, so such lists presumably could be required by regulation. Also repeals current law provisions requiring industry-wide lists of ingredients to be submitted to HHS.	Does not expressly require manufacturers to provide additive information to HHS and repeals provision of current law requiring industry-wide lists of ingredients to be submitted to HHS.	Requires premarket disclosure to HHS of a complete list of each tobacco additive used in the manufacture of each tobacco product brand name and the range of the quantities of each such additive used by a manufacturer in all of its tobacco product brand names. In addition, for products currently on the market, such lists are required no later than 3 months after enactment; for new products, at least 3 months prior to the date of manufacturing, importing or packaging.
	No comparable provision.	No comparable provision.	Requires tobacco companies, at the request of the HHS Secretary, to provide the Secretary with information regarding the impact of tobacco additives on health.

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To Public:	Requires HHS, by regulation, at a minimum, to prescribe labeling requirements that deem a tobacco product "misbranded" under the FDCA if it does not provide a "list of chemical additives . . . found in tobacco products." Thus, all additives presumably must be disclosed.	Requires packages to state all of the ingredients contained in the product in descending order of prominence.	Requires HHS, by regulation, to prescribe disclosure requirements on packages or package inserts to adequately inform the public of the additives contained in tobacco product brands; deems products in violation of such requirements "misbranded," borrowing that term from the FDA, but not amending that Act; and provides that spices, flavorings, fragrances and colorings may be designated as such without specifically naming each.
CONSTITUENT: DISCLOSURE			
To Agency:	Does not expressly require manufacturers to provide constituent information and test results to HHS, but HHS could so require under its general regulatory authority, discussed above under "Advisory Committee."	Requires premarket disclosure to HHS, within the last 12 months, of a complete list of all tobacco product brands and requires that, prior to marketing, such products must be tested to establish the levels of tar, nicotine, carbon monoxide and other	Requires premarket disclosure to HHS of a complete list of all tobacco product brands and requires that, prior to marketing, such products must be tested to establish the levels of tar, nicotine and

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		tobacco smoke constituent, as determined by the Secretary if the Secretary determines that it is appropriate to inform the public about the health hazards of such constituent.	carbon monoxide (and not "other" constituents). Requires such lists to be submitted within the time periods referred to above under "Additive Disclosure to Agency."
To Public:	Requires HHS, by regulation, at a minimum, to prescribe labeling requirements that deem a product "misbranded" under the FDCA if it does not provide a "list of constituents found . . . in tobacco smoke." Thus, all constituents presumably must be disclosed.	Prohibits constituent information on product packages or in advertisements without the approval of HHS. Requires HHS to make public the constituent lists and test results provided to it, as discussed above under "Constituent Disclosure To Agency."	Requires HHS to promulgate regulations prescribing disclosure requirements on packages or package inserts to adequately inform the public about the levels of tar, nicotine and carbon monoxide (and not "other" constituents) and borrows the term "misbranded" from the FDCA, but does not amend that Act, to classify products failing to make such disclosure.
Low-Tar/Nicotine Claims:	Requires HHS, by regulation, at a minimum, to deem a product "misbranded" under the FDCA if it contains implied/direct health claims, such as lower tar or nicotine free, unless the	Prohibits any representation in a tobacco ad or on a package regarding health or safety, including representations concerning the level of or removal, reduction or addition of ingredients, constituents,	No comparable provision.

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	HHS Secretary approves such term on the basis of sound scientific data and a determination that such term will have a significant impact on the health consequences of tobacco use.	filters or other devices. A tobacco ad, however, may contain such representation if the HHS Secretary determines, by regulation, that such claim is significant in affecting health and safety and is based on significant scientific agreement.	
NONTOBACCO NICOTINE CONTAINING PRODUCTS:	As mentioned above, requires HHS, by regulation, to treat as a "drug" under the FDCA any product containing nicotine, but not meeting the traditional definition of tobacco product, which is defined in the proposed bill to mean "cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, snuff and chewing tobacco."	No comparable provision.	Treats as a "drug" under the FDCA any product that contains nicotine, whether or not it also contains tobacco, but not meeting the traditional definition of tobacco product, which is defined in the proposed bill to mean "cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, and snuff, "and any other product that consists primarily of tobacco, is intended for human consumption, and is marketed for tobacco or smoking pleasure only."

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CONFECTIONARY:	No comparable provision.	Amends the FDCA to define as "misbranded" a confectionery or chewing gum "sold in a form which resembles cigarettes or other tobacco products."	No comparable provision.
ADULTERATION:	No comparable provision.	No comparable provision.	Prohibits "adulteration" of tobacco products (e.g., the product contains any filthy, putrid or decomposed substance or it is prepared or packed under unsanitary conditions).
ENFORCEMENT:	Amends the FDCA to cover tobacco products and, by so doing, incorporates the FDCA's enforcement mechanisms, which include a panoply of tools, such as seizure, injunction and criminal and civil fines. Also expressly amends the	Establishes civil penalties of up to $100,000 for each violation per day and provides injunctive relief.	Same as Synar bill, except adopts by reference the enforcement provisions of the FDCA.

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FDCA to give the FDA the right to factory inspections, as well as access to all records showing movement of tobacco products in interstate commerce. (Currently this authority exists for foods, drugs and cosmetics.)		
No comparable provision	Allows nonprofit, anti-tobacco groups to seek injunctive relief for violations of the proposed Act and to obtain court costs and attorney's fees if successful.	Allows individuals and organizations to bring civil suits against retailers and distributors of tobacco products to enforce the provisions of the proposed Act. Injunctive relief, monetary damages and attorney's fees may be awarded as a result of such suits.
No comparable provision.	No comparable provision.	Also includes penalties for violations by retail establishments and distributors of tobacco products in "Model States," as described below, including denial of delivery, shipping bans

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			and seizure of products.
WARNINGS/LABELING:*			
Sale to Minors:	Requires the warning: "Federal Law Prohibits Sale to Minors."	No comparable provision. (But see state requirements discussed below.)	No comparable provision. (But see "Model State" program below).
Additional Information:	Allows HHS, by regulation, to provide consumers with additional information (e.g., by way of inserts and additional labeling) about the adverse effects of tobacco products, adequate warnings and directions for use, contraindications, adequate warnings against use in pathological conditions and any information the Secretary deems necessary.	Generally the same as Synar bill.	Provides that nothing in the proposed bill or the Federal Cigarette Labelling and Advertising Act ("FCLAA") shall prohibit tobacco manufactures from providing consumers with information about the adverse effects of tobacco products beyond what is required under the law.

*Note that, under the general authority granted to HHS to promulgate regulations to govern the "labeling" of tobacco products, HHS could expand upon the minimum requirements specified in the Synar bill.

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Modifications:	Authorizes HHS to modify the warnings currently required under FCLAA, so long as such modifications do not weaken health messages and are in best interests of the public health.	No comparable provision.	No comparable provision.
Size and Placement:	HHS may, by regulation, increase the size and placement of required warning labels.	(Covers packages and ads.) Requires warning to appear on the top of the two most prominent sides (i.e., front and back) of the package; to occupy at least 25% of such side (20% for ads); to appear in white letters on black backing (or black on white), except that "WARNING" must be in red; to include letters thate are no less legible or prominent than other print on the package.	(Covers packages only) Requires warning to appear on two most prominent sides of the package; to occupy at least 20 percent of such side; and to include letters that are no less legible or prominent than other print on the package.
False Representations:	No comparable provision.	No comparable provision.	Prohibits the false representation or suggestion that an approval of a tobacco product is in effect under the proposed Act.

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New Warnings:	Replaces carbon monoxide warning with one on addiction. Requires HHS, by regulation, at a minimum, to deem a product "misbranded" under the FDCA if it does not include a warning about the dangers of ETS and does not contain the proposed new warning requirements as well as those required under current law (FCLAA).	Creates new warnings (nine in all), including "Cigarettes Kill," an addiction warning and one on the dangers of ETS.	Replaces carbon monoxide warning with one on addiction.
Tombstone Packages:	No comparable provision.	Prohibits packages from containing a picture or human/cartoon figure or facsimile thereof, unless such picture, etc. appeared on such package for 5 consecutive years before Jan. 1, 1989 (the year before the proposed Act was introduced).	No comparable provision.
Construction:	Provides that the regulations promulgated with respect to the advertising/promotion of tobacco products shall not repeal or modify the Federal Trade Commission (FTC)'s authority.	Provides that the proposed Act shall not be construed to limit or restrict the FTC's existing authority over tobacco products or promotion.	Provides that nothing in the proposed Act shall be construed to limit, restrict or expand the FTC's authority.

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ADVERTISING:*			
Content Restrictions:	Requires that regulations promulgated by HHS regarding advertising/promotion of tobacco products, at a minimum, must be consistent with those governing prescription drugs, especially drugs containing nicotine. (See also warning requirements, discussed above.)	Allows "tombstone" ads only: no human/cartoon figures or facsimiles thereof, no tobacco product trademark or logo and no picture other than a single package of the product being advertised displayed against a neutral white background. The print in any ad must be black on a white background. (See also warning requirements, discussed above.)	No comparable provision (except, see warning requirements, discussed above).
Location Restrictions:	See "Event Sponsorship" under "Promotion" below.	Prohibits ads within 1,000 feet of any school attended regularly by students under 21; in or on sports facilities; and on cars, boats or other sporting equipment. Also, no ads on T.V., radio, audiotape, audio disc, videotape, filing or video arcade games.	See "Preemption" below (allows states/localities to restrict the placement or location of billboards and transit advertising).

* Note that, under the general authority granted to HHS to promulgate regulations to govern the "advertising and promotion" of tobacco products, HHS would expand upon the minimum requirements specified in the Synar bill.

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PROMOTION:			
Event Sponsorship:	Requires HHS' regulations, at a minimum, to prohibit tobacco company sponsorship of any sporting, cultural or other event open to the public by a company that, at such event, displays the name or logo of any tobacco product brand.	Prohibits sponsorship of any event in the name of a tobacco product trademark (i.e., name, logo, symbol or other device to distinguish type or source of goods), or in a way that identifies or associates the trademark with the event.	No comparable provision.
Nontobacco Articles:	No comparable provision.	Prohibits marketing of nontobacco products (including toys) or services which bear the name of a tobacco product trademark.	No comparable provision.
Paid Product Placement:	No comparable provision.	Prohibits paying, or causing to to be paid, to have any tobacco product trademark appear in any movie, music video, T.V. show, play, video arcade game, other form of entertainment or on any sports equipment.	No comparable provision.
PREEMPTION:	Repeals 15 U.S.C. § 1334(b), as a "conforming amendment," which has the effect of repealing preemption of state tort law claims, but retaining preemption of	Repeals preemption provision of current law and, in its place, only would prohibit federal agencies, states and local regulatory bodies from requiring warnings in addition	Provides that nothing in the proposed Act or current law shall be interpreted to relieve tobacco manufacturers from liability under state

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	statements on smoking and health other than those required by 15 U.S.C. § 1333 (i.e., the four warnings).	to those required under current lawl. Also provides that nothing in the proposed Act or current law shall be interpreted to relieve tobacco manufacturers from liability under state common or statutory law (i.e., repeals preemption as a defense in product liability suits).	common or statutory law (i.e., repeals preemption as a defense in product liability suits).
SALE AND DISTRIBUTION:*			
Sale to Minors:	Creates a federal minimum age (at an age to be determined by each state).	States suffer the loss of federal funds if they do not enact a law (i) prohibiting sales to persons under age 19; (ii) requiring retailer licensing; (iii) requiring the posting of a notice concerning minimum age and a demand for photo-ID proof of age; (iv) prohibiting vending machines in a place where someone under 19 may lawfully enter without an adult; (v) including civil penalties and license suspension and revocation; and (vi) designating a state agency to issue licenses and enforce the law.	See "Model State" program discussed below. Model states must have in effect a law that prohibits the sale of tobacco products to persons under the age of 18.

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* Note that, under the general authority granted to HHS to promulgate regulations to govern the "sale and

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Sampling/ Coupons:	Prohibits free samples of tobacco products, coupons and other materials providing free or discounted tobacco products.	Same as Synar bill.	See "Model State" program discussed below. Model states must have, or seek to establish, a law prohibiting free samples of tobacco product.
Enforcement:	HHS must enforce the sale/ distribution restrictions in a manner that can reasonably be expected to ensure that tobacco products are not available to individuals under the age of 18.	States to specify. But injunctions may be brought in federal district court and private organizations may sue.	Generally, rests with the state, but the proposed Act includes a number of enforcement measures involving federal assistance (e.g., seizure by HHS of products from distributors who ship products to retail establishments held in violation of the prohibition on sales to minors, if such distributors violate the state's temporary ban on such shipments). Moreover, as described below under the "Model State program,"

[Footnote continued from previous page]
distribution" of tobacco products, HHS could expand upon the minimum requirements specified in the Synar bill.

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			the state may request federal assistance in enforcing the ban on the sale of tobacco products to minors.
"Model State" Program:	No comparable program, but see above for federal restrictions on the sale and distribution of tobacco products.	No comparable provision, but, as mentioned above, threatens the loss of federal funds to states that do not enact laws restricting sale/distribution of tobacco products.	Awards 10 to 20 states with model state leadership incentive grants to support activities that prevent the initiation of tobacco use and enforce existing state laws on the sale of tobacco products to minors. To be designated a model state, a state must have in effect a law that prohibits sales to persons under age 18 and must seek to improve the enforcement of the law. It also must have in effect a law or regulation to reduce the use of, or access to, vending machines by minors and must have in effect, or seek to establish, a (i) mechanism for reporting of citizen complaints concerning retail establishments that violate the state's minors law; (ii) a procedure by which the state may make a finding

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			or presumption that the retail establishment has a pattern or practice of violating the state's minors law; and (iii) a procedure by which it can request the assistance of the federal Office of Regulatory Affairs in order to better enforce its laws. The Office of Regulatory Affairs may assist the Model State in its enforcement functions, which include measures such as shipping bans and product seizures.
Partial Repeal of Preemption:	No comparable provision (but see "Preemption" above)	No comparable provision (but see "Preemption" above.)	Provides that, notwithstanding FCLAA or the Comprehensive Smokeless Tobacco Health Education Act, states and localities may enact additional restrictions on the (i) sale/distribution of tobacco products (including controls on vending machines and sampling); and (ii) placement and location of billboards and transit advertising of tobacco products to the extent

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			consistent with the First Amendment. (See also "Preemption" above.)
EDUCATIONAL AND RESEARCH ACTIVITIES:	No comparable provision.	Authorizes Center on Tobacco and Health to educate the public about the health effects of tobacco products; support research projects concerning the patterns of tobacco use by persons under age 21; prepare/distribute materials to educate the public; prepare public service announcements and conduct paid ad campaigns to discourage tobacco use by populations "at risk" (e.g., youth); coordinate discussions between the media and others regarding the impact of the media on tobacco use; and so on.	Requires HHS, acting through the newly created Center on Tobacco and Health within the Centers for Disease Control and in cooperation with non-federal entities, to carry out education and research activities that include, among other things, (1) the preparation of public service announcements and paid ads to inform the public about the health effects of tobacco products and passive smoke; (ii) the provision of information to the media regarding its role in promoting tobacco use; and (iii) the review of the rotating warning system.
PUBLIC INFORMATION CAMPAIGNS:	No comparable provision.	No comparable provision.	Requires HHS to make grants to (or enter into contracts with) public and nonprofit private entities to conduct public information campaigns -- through, for example, public service

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			announcements, print media, transit advertising, billboards and radio and television -- concerning the use of tobacco products. These campaigns should be aimed at youth, school dropouts, pregnant women, minorities, blue collar workers and low-income individuals. And, they should be aimed at countering tobacco ads.
WORKPLACE EDUCATION:	No comparable provision.	No comparable provision.	Requires HHS to make grants to (or enter into contracts with) public and nonprofit entities (including employer organizations and employer and employee consortia) for educational activities to reduce the use of tobacco products among workers with high prevalences of tobacco use.

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SCHOOLS:			
Grants to Health and Education Departments:	No comparable provision.	No comparable provision.	Authorizes HHS to make grants to (or enter into contracts with) state and local health and education departments and other public entities to assist them in implementing programs to prevent tobacco use in the schools.
Drug Abuse Programs:	No comparable provision.	No comparable provision.	Amends the Drug-Free Schools and Communities Act of 1986 to target tobacco use in addition to alcohol and drug abuse.
Smoke-Free Schools:	No comparable provision.	No comparable provision.	Authorizes the Secretary of Education to make grants to state education agencies for the establishment of smoke-free schools. To receive a grant, a state must: (i) create smoke-free school buildings, grounds and buses; (ii) require schools to establish smoking areas for adults only; and (iii) protect students from exposure to smoke. States are expressly permitted to place additional

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			restrictions on the use of tobacco products in schools.
PESTICIDE STUDY:	No comparable provision.	No comparable provision.	Require HHS, in consultation with the Secretary of Agriculture, to conduct a study of pesticides in tobacco products -- i.e., analyze the health effects of such pesticides and address whether tolerances should be established -- and report to Congress within one year of enactment.
FINDINGS:	Includes a number of negative findings, including that ETS is a cause of disease in nonsmokers; tobacco is as addictive as cocaine and heroin; each day 3,000 "children" buy cigarettes and become life-long addicted smokers; there is no federal minimum age; the industry adds chemicals to their products that are neither disclosed to the public nor tested; there is no testing of chemical	Also includes a series of negative findings, mostly focused on the tobacco industry's advertising and promotional practices.	Also includes a series of negative findings, mostly focused on education and sales to minors.

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components in smoke (e.g., the bill lists benzine, arsenic, cyanide); and it is inconsistent for the FDA to regulate other nicotine-containing products and not tobacco products.